

REMARKS

Applicants have received and carefully reviewed the Final Action of the Examiner mailed February 12, 2003. Claims 1-15, 17-22, 24-42, 44-48, 50-56, 58 and 59 remain pending, with all claims presently rejected. Reconsideration and reexamination in light of the following remarks are respectfully requested.

In paragraph 3 of the Final Action, the Examiner rejected claims 1-9, 13-15, 17-22, 24-27, 31-37, 40-42, 44-48, 50-56 and 58-59 under 35 U.S.C. §103(a) as being unpatentable over Samson, U.S. Patent No. 5,702,373 in view of Cook, U.S. Patent No. 4,637,396. As set forth in the previous Amendment, Applicants believe that the cited combination is impermissible as lacking a motivation for making the cited combination. Applicants again submit that the cited combination is impermissible at least because there is no suggestion to take a knitted member as suggested for preventing balloon over-inflation by Cook for use in the braided catheter of Samson. Reconsideration is requested.

The Examiner has stated repeatedly that Samson does not suggest the knitted member recited in Applicants independent claim 1. The Examiner cites Cook as suggesting a knitted reinforcing member. However, Applicants submit that there is a significant difference between reinforcing a catheter as suggested by Samson to provide anti-kink and torquing characteristics necessary for relatively long and thin interventional catheters, and reinforcing a balloon, which is performed by Cook to prevent overinflation and potential bursting of the balloon. The reinforcing members are provided for different purposes. Further, the reinforcing members perform their function quite differently. In particular, the braided member of Samson is intended to provide support against pressure applied on the outside of a catheter wall in which the braided member of Samson is provided. The knitted member of Cook is provided to provide support

against pressure applied on the inside of an inflatable balloon, as well as to provide elasticity to the balloon to allow it to fully deflate and achieve a low profile while deflated.

In the response to arguments, the Examiner has traversed the Applicants' arguments with respect to the characterization of the Cook reference. The Examiner states, "the knitted member taught by Cook is not necessarily expandable." Applicants respectfully disagree, and submit that Cook clearly teaches an expandable element. Cook states "Referring to FIG. 4, there is shown in detail the configuration of a portion of knitted middle layer 23 in an expanded state." Column 2, lines 57-59. Applicants respectfully submit that one would not characterize an element as being "in an expanded state" if it is not expandable. Further, Cook clearly explains that the knitted member is in fact expandable, and the mechanism which allows expansion:

The yarn strand 39 of which middle layer 23 is knitted is comprised of multiple plies or filaments. In the preferred embodiment, the yarn strand is comprised of two parallel twisted plies, one ply 39A being strong and inelastic for limiting the maximum expanded diameter of the balloon, and the other ply 39B being elastic for contracting the balloon when inflation pressure is absent.

Column 3, lines 10-17. Then:

Middle layer 23 is knitted loosely with the Spandex plies being stretched during knitting so that after the tube is knitted, the Spandex strands contract and collapse middle layer 23 into its normal configuration. Thereafter, when balloon 12 is expanded, knitted middle layer 23 expands in diameter until all of the loops are pulled taut (as shown in FIG. 4), at which point knitted layer 23 will expand no further because of the inelastic nature of the Kevlar plies.

Column 3, lines 22-31. Not only is the knitted member expandable, but Cook clearly explains how such expansion and subsequent contraction is performed.

Applicants appreciate the explanation given by the Examiner on pages 4-5 of the Final Action with respect to the modification of Cook addressed in the previous Office Action, which explanation clarifies the present issues. However, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness because there is no suggestion how one of

skill in the art could observe Cook, which illustrates a knitted layer having elastic and inelastic plies in the knitting yarn used to limit outward expansion of a balloon, and determine that the expandable knitting of Cook should be substituted for a braided ribbon support member as in Samson. Applicants, as well as the Examiner, have found no place in Samson that suggests use of a knitted member. Applicants further note that Cook distinguishes the usefulness of a braid to perform the expansion limiting function of a knitted member:

The Hanecka balloon is reinforced by a woven synthetic fabric wherein the filaments of the fabric extend along helices of the opposite sense. As stated in the patent, such a reinforced balloon shortens in length with an increase in diameter. Therefore, to prevent folds in the balloon when it is deflated, the Hanecka device employs two coaxial tubes, one slideable within the other, for lengthening the balloon when it is deflated and permitting shortening of the balloon as it is inflated. One disadvantage of such a balloon catheter is that the structure requires components or parts which are movable relative to one another.

The present invention provides a reinforced inflatable balloon which is smooth in its deflated state, yet expands in diameter without decreasing in length.

Column 1, lines 21-42. Thus Cook is stating that for the purpose of reinforcing a balloon, a knitted member as disclosed by Cook performs the function differently from a braided member. Hence a knitted member performs distinct functions in different manners from a braided member, according to Cook.

Applicants further note that incorporating the teachings of Cook to Samson would suggest incorporating the advantages identified by Cook into the catheter of Samson. Thus, the suggested combination would result in a modified catheter similar to that suggested by Samson, except that the catheter would be radially expandable without reducing in length. It does not appear to Applicants that Samson has identified any reason whatsoever for providing a catheter which is radially expandable without reducing in length. Thus, not only is the specific structure of Cook not suggested by Samson, the purpose of the structure is not identified as advantageous. Given distinct purposes and the fact that at least one of the cited references clearly distinguishes

the utility of the two structures, Applicants believe that the disclosures themselves provide no motivation to combine.

The Examiner, instead of relying on either the disclosure of Cook or the disclosure of Samson, quotes MPEP §706.02(j). “First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings” Then, on page 6 of the Office Action, the Examiner states, “It is the Examiner’s position that knitted members used for reinforcement to prevent kinking or to inherently add rigidity is knowledge generally available to one of ordinary skill in the art.”

Although language expressly relying on this portion of the MPEP is not included in the rejection, Applicants take the above to be a statement that the Examiner believes that the use of knitted members are providing reinforcement to prevent kinking or to add rigidity to a catheter shaft (which one of skill in the art would clearly understand as the meaning and purpose of a reinforcing layer for a catheter shaft) is well known in the prior art under MPEP 2144.03. Applicants previous Amendment filed November 27, 2002 stated the following on page 5:

Finally, as noted in the previous paragraph, the knitted reinforcing member suggested by Cook has a different purpose than the braided reinforcement member suggested by Samson, in light thereof, Applicants respectfully disagree with the Examiner’s contention that a knitted reinforcing member was known to be “equivalent” to a braided reinforcing member.

Amendment at page 5. Applicants again traverse this assertion and remind the Examiner that “if the applicant traverses such an assertion the examiner should cite a reference in support of his or her position.” MPEP 2144.03. It is requested that, in accordance with the MPEP, the Examiner produce a reference that supports the Examiner’s position. It is believed that with the above reprinted statement, Applicants did indeed previously traverse the Examiner’s rejection on these

grounds, and a reference should have been supplied with the Final Action. In light thereof, Applicants request that the finality of the action be withdrawn.

If the Examiner is basing support for the present rejections on some other portion of the MPEP, Applicants respectfully request that the Examiner make explicit the basis for the Examiner's contentions within the confines of the MPEP. It is sincerely believed that the above is an accurate characterization of the Examiner's rejection, and that the rejection is overcome with these remarks because the proposed substitution of a knitted member for a braided member is not widely or well known in the art. However, if the Examiner is not relying on MPEP 2144.03 to make the present rejections, a clear specification of the basis for combination which the Examiner is relying upon is requested to allow Applicants to fully evaluate whether filing a Notice of Appeal is appropriate.

As the cited combination forms the basis for rejections of each of claims 1-9, 13-15, 17-22, 24-27, 31-37, 40-42, 44-48, 50-56 and 58-59, Applicants believe that each of the claims is clearly patentable over the impermissible combination in light of the above remarks.

In paragraph 4 of the Final Action, the Examiner rejected claims 10-12, 28-30, and 38-39 under 35 U.S.C. §103(a) as being unpatentable over Samson in view of Cook and further in view of Samson et al., U.S. Patent No. 5,549,109. As noted above, Applicants believe that the combination of Samson in view of Cook lacks motivation to combine and is, therefore, impermissible. Applicants note that Samson et al. is cited by the Examiner solely to suggest a multi-filament wire. Therefore, it does not appear that the Examiner has established a motivation to combine yet another reference with the impermissible combination of Samson in view of Cook.

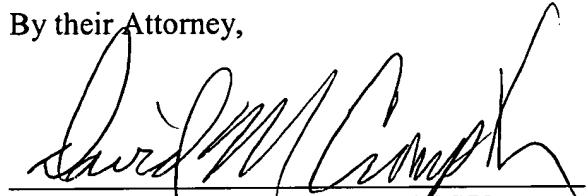
In light of the above remarks, Applicants also believe that each of claims 10-12, 28-30, and 38-39 are all clearly patentable over the impermissible combination.

Reconsideration and reexamination are respectfully requested. It is submitted that all pending claims 1-15, 17-22, 24-38, 50-56 and 58-59 are in condition for allowance. Issuance of a Notice of Allowance in due course is respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully Submitted,

Jill McFadden et al.

By their Attorney,



David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349



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